

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

In the specification, paragraphs have been amended on pages 1 and 5.

Claims 18-38 are pending in the application. Claims 34 and 38 have been withdrawn from consideration.

Objection to the Specification

The specification is objected to for containing informalities. Applicant respectfully submits that the amendments to the specification render this objection moot. Reconsideration and withdrawal of this objection is respectfully requested.

Rejections under 35 U.S.C. § 103

Claims 18, 19, and 21-27

Claims 18, 19, and 21-27 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,465,226 to Zimmermann (hereafter "Zimmermann") in view of "Ultrasonic Atomization for Spray Drying: A Versatile Technique for the Preparation of Protein Loaded Biodegradable Microspheres" to Bittner *et al.* (hereafter "Bittner"). This rejection is respectfully traversed.

Zimmermann discloses a process of preparing microcapsules that contain active substances by providing a spray nozzle with two channels, with one channel being impinged by air and the other by a solution. See Zimmermann at col. 1, lines 7-11, and col. 2, lines 10-21. Zimmermann discloses that air flow from the first channel of the spray nozzle causes droplets to break off at a specific size and that by selecting the air pressure, channel diameter of the spray nozzle, and flow rate of the solution, the ratio of the droplet volume to core volume can be controlled. See Zimmermann at col. 2, lines 21-28.

The Office argues on pages 3-4 of the Office Action that Zimmermann discloses the process of claim 18 except that Zimmermann does not explicitly disclose a gas stream as being continuous and does not disclose or suggest the use of an ultrasonic nebulizer, as recited in claim 18. Claims 19 and 21-27 depend from claim 18.

The Office argues on page 4 of the Office Action that Bittner discloses ultrasonic atomization to prepare microspheres and that it would have been obvious to one of ordinary skill to modify the process of Zimmermann to use the ultrasonic atomization disclosed by Bittner. Applicant respectfully disagrees.

One of ordinary skill in the art would not have modified the process of Zimmermann by the teachings of Bittner, as argued by the Office, because such a modification is contrary to the teachings of Zimmermann. Zimmermann discloses that the central idea of Zimmermann's process is to use a spray nozzle with two channels, not ultrasonic atomization. See Zimmermann at col. 2, lines 1-28.

Furthermore, a proposed modification cannot change the principle of operation of a reference. See MPEP § 2143.01, Part VI. The modification suggested by the Office would require a complete re-design of the spray nozzle construction disclosed by Zimmermann, which would be a severe deviation from the teachings of Zimmermann. For example, if the construction disclosed by Zimmermann were modified to use an ultrasonic atomizer the construction would no longer be capable of control the ratio of droplet volume to core volume by controlling an air pressure of an air flow, as disclosed by Zimmermann. Thus, the teachings of Bittner are not compatible with those of Zimmermann.

In addition, Zimmermann teaches that a pressure of 40 mbar is used. See Zimmermann at col. 3, lines 4-15. Rather large, voluminous droplets would be expected with such a relatively low pressure. In fact, Zimmermann describes the solution as being "dropped" from the nozzle in col. 3, lines 16-20, rather than being sprayed. This suggests that a stream would be generated from the nozzle rather than single droplets. Conversely, spray particles tend to float rather than drop and are guided by a flow of air. Zimmermann does not disclose or suggest that Zimmermann's preferred nozzle produces such droplets or particles. The design disclosed by Zimmermann appears to produce droplets with a size of 100-300 microns rather than spray droplets that typically have a size of 10-20 microns. Furthermore, the size of typical spray droplets would be too small of the cells that Zimmermann desires, which contain active material. Thus, the teachings of Zimmermann demonstrate that the process of Zimmermann is intended to produce large droplets, not a spray of small droplets.

For at least the reasons discussed above, one of ordinary skill in the art would not have modified the process of Zimmermann by the teachings of Bittner because such a

modification would have changed the principle of operation of the process of Zimmermann and would not have been compatible with the teachings of Zimmermann. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 20 and 28

Claims 20 and 28 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Zimmermann and Bittner and further in view of U.S. Patent No. 4,352,883 to Lim (hereafter “Lim”). This rejection is respectfully traversed. Lim fails to remedy the deficiencies of Zimmermann and Bittner discussed above in regard to independent claim 18, from which claims 20 and 28 depend. Reconsideration and withdrawal of this rejection is respectfully requested.

Claims 29, 30, 32, and 35-37

Claims 29, 30, 32, and 35-37 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Zimmermann and Bittner and further in view of WO 03/091315 to Andersson *et al.* (hereafter “Andersson”). This rejection is respectfully traversed. Andersson fails to remedy the deficiencies of Zimmermann and Bittner discussed above in regard to independent claim 18, from which claims 29, 30, 32, and 35-37 depend. Reconsideration and withdrawal of this rejection is respectfully requested.

Claim 31

Claim 31 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Zimmermann, Bittner, and Andersson and further in view of “Preparation and Characterization of Alginate Microspheres Containing a Model Antigen” to Lemoine *et al.* (hereafter “Lemoine”). This rejection is respectfully traversed. Lemoine fails to remedy the deficiencies of Zimmermann, Bittner, and Andersson discussed above in regard to independent claim 18, from which claim 31 depends. Reconsideration and withdrawal of this rejection is respectfully requested.

Claim 33

Claim 33 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Zimmermann and Bittner and further in view of U.S. Patent No. 5,387,522 to Vasington *et al.*

(hereafter "Vasington"), Andersson, and Lemoine. This rejection is respectfully traversed. Vasington, Andersson, and Lemoine fail to remedy the deficiencies of Zimmermann and Bittner discussed above in regard to independent claim 18, from which claim 33 depends. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicant submits that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By P.D.S.

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